

supersedes the "Nuclear Pharmacy Guideline; Criteria for Determining When to Register as a Drug Establishment" issued by FDA in May 1984.

A. Physiological Research

Facilities using PET radiopharmaceuticals for purely physiological research, where the results of such research are not used to guide patient management or treatment decisions, should establish a PET Regulatory Committee (PRC) in accordance with §1A361.1 *Radioactive drugs for certain research uses* (21 CFR 361.1). The PRC will monitor all physiological research of the PET facility. Facilities using PET radiopharmaceuticals for purely physiological research are not required to submit an investigational new drug application (IND) or NDA as long as this research is intended to obtain basic information regarding metabolism or physiology and is not intended to guide or be part of therapeutic, diagnostic, or clinical management plans.

FDA will approve and monitor the PRC, which should consist of at least five individuals. In accordance with §1A361.1(c), each PRC should include: (1) A physician recognized as a specialist in nuclear medicine; (2) a person qualified by training and experience to manufacture PET radiopharmaceuticals; and (3) a person with special competence in radiation safety and radiation dosimetry. The remaining PRC members should include individuals qualified in various disciplines pertaining to the field of nuclear medicine, and should be sufficiently diverse to permit expert review of the technical and scientific aspects of proposals submitted to the committee. In addition to the requirements in §1A361.1(c) and with the exception of the member qualified by training and experience to manufacture PET radiopharmaceuticals, PRC membership should include a representative of a consumer group, and the members should not have scientific, clinical, financial, or administrative conflicts of interest.

The PRC should have three main responsibilities: (1) To approve research protocols; (2) to prepare annual reports; and (3) to determine when purely physiological research has ended.

In approving protocols, the PRC should: (1) Determine if the investigator meets the qualifications specified in the protocol; (2) review the research protocol design; (3) review and monitor the selection of research subjects; (4) ensure that the research subjects have signed informed consent documents; (5)

review and monitor the quality of the PET radiopharmaceuticals administered; (6) evaluate all reports of adverse events; and (7) confirm concurrence of Institutional Review Board approval.

The annual report should follow the format and contents prescribed in §1A361.1(c)(3), summarizing the conditions of use, doses, route of administration, protocols, adverse events reported in the safety information, and the chemistry, manufacturing, and control data. The PRC should submit the completed annual report to FDA.

The PRC is also responsible for determining when purely physiological research becomes investigational clinical use. This determination should be based on whether the data obtained will be used in the diagnostic, therapeutic, or clinical management of patients. Once trials are proposed for investigational clinical use, the facility must submit an IND before starting to conduct the trials.

B. Investigational Use

Manufacturers of PET radiopharmaceuticals intended to be used in investigational clinical trials must submit an IND to FDA in accordance with the regulations in part 312. Institutions or investigators working together with the same PET radiopharmaceutical may submit one IND for that drug product, covering studies conducted at more than one site or institution.

C. NDA Approval

Submission of an NDA, in accordance with FDA regulations in part 314 (21 CFR part 314), is required for PET radiopharmaceuticals used in clinical practice. Institutions or investigators working together with the same PET radiopharmaceutical may submit one NDA for that drug product. All sites that produce the same drug product would be covered by the submitted NDA. Once an NDA is approved, other PET facilities with a radiopharmaceutical that is an equivalent finished product, but which did not participate in the NDA or did not submit manufacturing data, could submit an abbreviated new drug application (ANDA) demonstrating that their drug is bioequivalent to the innovator drug, in accordance with FDA regulations in part 314. Alternatively, the NDA holder could submit a supplement to add these other facilities as new manufacturing sites.

PET radiopharmaceuticals are also subject to the adulteration and misbranding provisions of the act. Facilities where PET

radiopharmaceuticals are manufactured are subject to inspection by FDA for compliance with CGMP requirements and other drug-related requirements.

Dated: February 17, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-4691 Filed 2-24-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-55-3710; FR-3636-03]

Announcement of Funding Awards Public Housing Drug Elimination Technical Assistance Program, FY 1994

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Notice of Funding Availability (NOFA) for Public Housing Drug Elimination-Technical Assistance Program. This announcement contains the names and addresses of the award winners and the amount of the awards.

FOR FURTHER INFORMATION CONTACT: Elizabeth Cocke, Drug Free Neighborhoods Division, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4116, Washington, DC 20410, telephone (202) 708-1197. A telecommunications device for hearing or speech impaired persons (TDD) is available at (202) 708-0850. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The Public Housing Drug Elimination-Technical Assistance Program is authorized by the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1994 (approved October 28, 1993, Pub. L. 103-124).

The NOFA published in the Federal Register on March 10, 1994 (59 FR 11418) announced the FY 1994 availability of \$1,255,175 to fund qualified applicants selected under the FY 1993 NOFA and invited additional applicants for FY 1994. The purpose of

the program is to provide short-term technical assistance to public housing agencies, Indian housing authorities, resident management corporations, and incorporated resident councils that are combating abuse of controlled substances in public and Indian housing communities. These funds reimburse consultants who provide expert advice and work with housing authorities or resident councils to assist them in

gaining skills and training to eliminate drug abuse and related problems from public housing communities. Applications were scored and selected for funding for the third and fourth quarter based on criteria contained in the Notice.

In accordance with section 102 (a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235, approved

December 15, 1989), the Department is publishing the names and addresses of the recipients which received funding under this NOFA, and the amount of funds awarded to each. This information is provided in Appendix A to this document.

Dated: February 21, 1995.
Joseph Shuldiner,
Assistant Secretary for Public and Indian Housing.

APPENDIX A.—FISCAL YEAR 1994 PUBLIC AND INDIAN HOUSING RECIPIENTS OF THIRD AND FOURTH QUARTER FUNDING DECISIONS

Name and address	Amount awarded
PROGRAM NAME: Public Housing Drug Elimination Technical Assistance Program STATUTE: Public Law 103-124, October 28, 1993.	
MIDTOWN TERRACE RESIDENT COUNCIL, WV, LILLIAN YOUNG, 1447 Peachtree Street, #522, Atlanta, GA 30309	\$8,937.00
COLLEGE PARK HOUSING AUTHORITY, GA, ANTHONY RANDOLPH, 1050 Topeka Street Pasadena, CA 91104	9,807.00
MONTICELLO HOUSING AUTHORITY, NY, ROBERT BORGHESE, 21 S. 12th St. Suite 902, Philadelphia, PA 19107	8,686.00
APACHE MANOR RESIDENT COUNCIL, OK, IAN HORNCastle, 830 South Woodlawn Ave., Okmulgee, OK 74447	10,000.00
SANDY PARK RESIDENT ASSOCIATION, OK, GLENN MCCURDY, 7942 Park Avenue, Elkins Park, PA 19117	5,741.00
MAKAH INDIAN HOUSING AUTHORITY, WA, GARY LIMING, 19707-44th Ave., W. Suite 212, Lynwood, WA 98036	6,654.00
PONTIAC HOUSING COMMISSION, MI, RONALD SIMPKINS, Commitment To Character, P.O. BOX 157151, Cincinnati, OH 45215	5,444.00
CRESTVIEW HOUSING AUTHORITY, FL, PAUL TANNER, 5618 Shorewood Road, Jacksonville, FL 32210	8,776.00
HOUSING AUTHORITY OF TOWN, OF SOUTH KINGSTOWN, RI, SUSAN BARRY, SYMPATICO INC., 57 Columbia Street, Wakefield, RI 02879	8,425.00
HOUSING AUTHORITY OF THE CITY OF ASHEVILLE, NC, RICHARD MARTIN, P.O. Box 12311, Raleigh, NC 27605	8,737.00
NORTH WILKESBORO DEPT. OF HOUSING, NC, JOHN T. PHILLIPS, 302 North Lee Street, Ayden, NC 28513	5,840.00
TACOMA HOUSING AUTHORITY, WA, EDWIN C. GOODWIN, National Facility Consultants, 1579-F Monroe Dr., NE, Suite 168, Atlanta, GA 30324	9,682.00
MESCALERO APACHE INDIAN HOUSING, AUTHORITY, NM, SUSAN GUYETTE, 97 Moya Rd., Santa Fe, NM 87505	8,618.00
GREENSBORO HOUSING AUTHORITY, AL, JOSEPH ALEX, P.O. BOX 210546, 4604 Virginia Loop Road, Montgomery, AL, 36121	8,510.00
STAMFORD HOUSING AUTHORITY, CT, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	9,930.00
ERNIE CRAGIN TERRACE RESIDENT COUNCIL, NV, PAUL TURNER, 410 Castello Road, Lafayette, CA 94549	9,915.00
NAVAJO HOUSING AUTHORITY, AZ, THOMAS WICKENDEN AND LAURENCE GISHEY, BOX 4132 Northern Arizona University, Flagstaff, AZ 86011-4132	7,424.00
OPELIKA HOUSING AUTHORITY, AL, JOSEPH ALEX, P.O. BOX 210546, 4604 Virginia Loop Road, Montgomery, AL 36121 ..	9,116.00
HOUSING AUTHORITY OF THE TOWN OF LAURINBURG, NC, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	7,407.00
KEY WEST HOUSING AUTHORITY, FL, JOHN DOYLE BANYAN PRODUCTIONS, 3134 Northside Drive, Key West, FL 33040	9,955.00
LITTLE ROCK HOUSING AUTHORITY, AR, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	9,758.00
SPOKANE HOUSING AUTHORITY, WA, JEFFREY OSHINS, 271 Rosario Park Road, Santa Barbara, CA 93105	9,143.00
LUMBERTON HOUSING AUTHORITY, MS, ROBERT TAYLOR, 425 Beasley Road, #B7, Jackson, MS 39286	8,073.00
UNIONTOWN HOUSING AUTHORITY, AL, JOSEPH ALEX, P.O. BOX 210546, 4604 Virginia Loop Road, Montgomery, AL 36121	5,864.00
CUMBERLAND PLATEAU REGIONAL HOUSING AUTHORITY, VA, GENEVA O'QUINN, Route 1, Box 601-A, Clintwood, VA 24228	4,725.00
CANTON HOUSING AUTHORITY, MS, ROBERT TAYLOR, 425 Beasley Road, #B7 Jackson, MS 39286	5,967.00
HOUSING AUTHORITY OF BAYTOWN, TX, ROBIN MITCHELL, FREEDOM COMMUNICATIONS, 512 East 11th, Suite 206, Austin, TX 78702	9,545.00
MANAHAN VILLAGE RESIDENT COUNCIL, NJ, WANDA W. STANSBURY, 206 Renfrew Ave., Trenton, NJ 08618	9,981.00
SMITHFIELD HOUSING AUTHORITY, NC, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	7,063.00
MASSENA HOUSING AUTHORITY, NY, ROBERT BORGHESE, 21 S. 12th St., Suite 902, Philadelphia, PA 19107	9,155.00
MONTGOMERY COUNTY HOUSING AUTHORITY, PA, WANDA W. STANSBURY, 206 Renfrew Ave., Trenton, NJ 08618	9,960.00
SOUTH HILLS TERRACE TENANTS ORGANIZATION, PA, DAVID BUCHES, RD 1 Box 735A, Dover, DE 19901	6,306.00
HOUSING AUTHORITY OF LAUREL, MS, ROBERT TAYLOR, 425 Beasley Road, #B7, Jackson, MS 39286	6,525.00
FORT WALTON BEACH HOUSING AUTHORITY, FL, JIM L. MUNRO, 7335 No. Shores Dr., Navarre, FL 32566	5,129.00
INKSTER HOUSING COMMISSION, MI, CURTIS JONES, 6 Lindsey Street, Dorchester, MA 02124	9,307.00
BLACKFEET INDIAN HOUSING AUTHORITY, MT, JEFFREY OSHINS, 271 Rosario Park Road, Santa Barbara, CA 93105	8,502.00
TURTLE MOUNTAIN INDIAN HOUSING AUTHORITY, SD, ANNE FALLIS, Rural Route 1, BOX 1845, Rapid City, SD 57702 ...	8,324.00
CHOCTAW NATION INDIAN HOUSING AUTHORITY, OK, RICARDO JASSO, P.O. Box 11615, Casa Grande, AZ 85230	8,624.00
HALL COUNTY HOUSING AUTHORITY, NE, GARY DAVIS, 620 Alum Creek Drive, Columbus, OH 43205	5,629.00
HOUSING AUTHORITY OF THE CITY OF PASCO AND FRANKLIN COUNTY, GWENDOLYN SHEPHERD, GMSS LEARNING SERVICES, 7060 McCormick Woods Dr. SW, Port Orchard, WA 98366-7645	8,900.00
TEMPLE HOUSING AUTHORITY, TX, KAI MARTENSEN, 706 Bridgeman Terrace, Towson, MD 21204	9,786.00
NORTHERN CHEYENNE INDIAN HOUSING AUTHORITY, MT, DEBRA WILLIAMS-HOUSE, Stone Mountain, GA	9,985.00
HOUSING AUTHORITY OF RICHMOND, CA, ROBERT REYNOLDS, 2131-2nd Ave., Los Angeles, CA 90018	9,436.00

APPENDIX A.—FISCAL YEAR 1994 PUBLIC AND INDIAN HOUSING RECIPIENTS OF THIRD AND FOURTH QUARTER FUNDING DECISIONS—Continued

Name and address	Amount awarded
DISTRICT OF COLUMBIA DEPARTMENT OF PUBLIC AND ASSISTED HOUSING, DC, ROBERT BORGHESE, 21 S. 12th St., Suite 902, Philadelphia, PA 19107	7,805.00
DISTRICT OF COLUMBIA DEPARTMENT OF PUBLIC AND ASSISTED HOUSING, DC, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	10,000.00
MUCKLESHOOT INDIAN HOUSING AUTHORITY, WA, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	10,000.00
HOUSING AUTHORITY OF BALTIMORE CITY, MD, DAVID ROUEN, TSAILE, INC. (PATH) Box 1827, Carolina Beach, NC 28428	5,496.00
DANBURY HOUSING AUTHORITY, CT, PATRICIA SURPRENANT, 418 Robin Ct., Cheshire, CT 06410	4,836.00
HOUSING AUTHORITY OF WINONA, MS, PAUL TANNER, 5618 Shorewood Rd., Jacksonville, FL 32210	9,018.00
FORT BERTHOLD INDIAN HOUSING AUTHORITY, ND, ANNE FALLIS, Rural Route 1, Box 1845, Rapid City, SD 57702	9,204.00
HATTIESBURG HOUSING AUTHORITY, MS, C. JEAN BENNETT, 207 Valley North Blvd., Jackson, MS 39206	8,084.00
FOREST HOUSING AUTHORITY, MS, C. JEAN BENNETT, 207 Valley North Blvd., Jackson, MS 39206	8,718.00
HOUSING AUTHORITY OF THE CITY OF NEW BERN, NC, LEXIE WILLIAMS, 1177 Dominion Court, Port Orange, FL 32119 .	7,240.00
HOUSING AUTHORITY OF GRANT COUNTY, WA, ROXANNA NANTO, CC CONSULTING ASSOCIATES, 704 NE Larch Court, Wenatchee, WA 98802	6,613.00
TAYLOR HOUSING AUTHORITY, TX, JAMES GODFREY, GODFREY & ASSOCIATES, P.O. Box 2470, Hot Springs, AR 71914	9,512.00
COLORADO RIVER INDIAN HOUSING AUTHORITY, AZ, SUSAN GUYETTE, 97 Moya Rd., Santa Fe, NM 87505	8,953.00
HOUSING AUTHORITY OF WOONSOCKET, RI, ROBERT BORGHESE, 21 S. 12th St., Suite 902, Philadelphia, PA 19107	9,132.00
ROME HOUSING AUTHORITY, GA, JAMES GODFREY, GODFREY & ASSOCIATES, P.O. Box 2470, Hot Springs, AR 71914	9,787.00
PROVIDENCE HOUSING AUTHORITY, RI, SEVERIN SORESENSEN, PO Box 34469, Bethesda, MD 20813-1072	10,000.00
CANTON HOUSING AUTHORITY, NY, LYNN BORRELL, Lynne Borrell & Associates, Suite 402, 1165 North Clarke, Chicago, IL 60610	10,000.00
THE HOUSING AUTHORITIES OF FAIRBURN/UNION CITY, GA, SAUNDRA D. WILLIAMS, D & J CONSULTANTS, 4300 Flat Shoals Road #2606, Union City, GA 30291	9,440.00
MARIANNA HOUSING AUTHORITY, FL, PAUL TANNER, 5618 Shorewood Road, Jacksonville, FL 32210	8,858.00
SCHWARTZ-ROBESON TENANTS ASSOCIATION, NJ, ALEXANDER SUTTON, 1133 Kensington Ave., Plainfield, NJ 07060 ..	10,000.00
HOUSING AUTHORITY OF GALLATIN, TN, KARRIEM SHABAZZ, 3150 Borge Street, Oakton, VA 22124	6,630.00
TRIANA HOUSING AUTHORITY, AL, JOSEPH ALEX, P.O. BOX 210546, 4604 Virginia Loop Road, Montgomery, AL 36121	8,355.00
PENNINGTON COURT TENANTS ASSOCIATION, NJ, GERARD LEE, 810 Belvidere Ave., Plainfield, NJ 07060	10,000.00
HOUSING AUTHORITY OF MERCED, CA, JEFFREY OSHINS, 271 Rosario Park Road, Santa Barbara, CA 93105	7,504.00
WILMINGTON HOUSING AUTHORITY, DE, NANCY LOWE-CONNO, 3406 Wild Cherry Road, Baltimore, MD 21207	9,959.00
SOUTHERN PUGET SOUND INDIAN HOUSING AUTHORITY, WALINDA RINALDI, Seattle, WA	9,786.00
HOUSING AUTHORITY OF JACKSON COUNTY OR ROXANNA NANTO, CC CONSULTING ASSOCIATES, 704 NE Larch Court, Wenatchee, WA 98802	9,441.00
OLNEY HOUSING AUTHORITY, TX, JEFFREY OSHINS, 271 Rosario Park Road, Santa Barbara, CA 93105	7,911.00
Total	595,673.00

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BILLING CODE 4210-33-P

Office of the Secretary

[Docket No. N-95-3892; FR-3864-N-01]

Notice of Regulatory Waiver Requests Granted

AGENCY: Office of the Secretary, HUD.

ACTION: Public notice of the granting of regulatory waivers. Request: July 1, 1994 through September 30, 1994.

SUMMARY: Under the Department of Housing and Urban Development Reform Act of 1989 (Reform Act), the Department (HUD) is required to make public all approval actions taken on waivers of regulations. This notice is the fifteenth in a series, being published on a quarterly basis, providing notification of waivers granted during the preceding reporting period. The purpose of this notice is to comply with the

requirements of section 106 of the Reform Act.

FOR FURTHER INFORMATION CONTACT:

For general information about this Notice, contact Camille E. Acevedo, Assistant General Counsel for Regulations, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410; (telephone 202-708-3055); TDD: (202) 708-3259. These are not toll-free numbers.) For information concerning a particular waiver action, about which public notice is provided in this document, contact the person whose name and address is set out, for the particular item, in the accompanying list of waiver-grant action.

SUPPLEMENTARY INFORMATION: As part of the Housing and Urban Development Reform Act of 1989, the Congress adopted, at HUD's request, legislation to limit and control the granting of regulatory waivers by the Department. Section 106 of the Act (Section 7(q)(3)

of the Department of Housing and Urban Development Act, 42 U.S.C. 3535 (q)(3), provides that:

1. Any waiver of a regulation must be in writing and must specify the grounds for approving the waiver;

2. Authority to approve a waiver of a regulation may be delegated by the Secretary only to an individual of Assistant Secretary rank or equivalent rank, and the person to whom authority to waive is delegated must also have authority to *issue* the particular regulation to be waived;

3. Not less than quarterly, the Secretary must notify the public of all waivers of regulations that the Department has approved, by publishing a Notice in the Federal Register. These Notices (each covering the period since the most recent previous notification) shall:

a. Identify the project, activity, or undertaking involved;